

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date	5/4/01 @ 4:54
Publication Date	5/9/01
Certifier	Romani Oliver

Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of the Committee: Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 21, 2001, 1 p.m. to 5 p.m., and May 22, 2001, 8 a.m. to 5 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Joyce M. Whang, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12524. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 21, 2001, the committee will discuss a supplement to a premarket approval application (PMA) for an intrapartum fetal pulse oximeter. The committee will also hear a presentation on the clinical trial of an intrapartum fundal pressure belt intended to reduce the

incidence of operative deliveries. On May 22, 2001, in the morning session, the committee will discuss air and gas emboli associated with operative hysteroscopy. In the afternoon session, the committee will discuss uterine artery embolization. Background information and questions to the committee will be available to the public on May 18, 2001, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

Procedure: On May 21, 2001, from 1 p.m. to 5 p.m. and May 22, 2001, from 10 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 11, 2001. On May 21, 2001, oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2 p.m., and on May 22, 2001, oral presentations from the public will be scheduled between approximately 11:30 a.m. and 11:45 a.m., and between approximately 2:45 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before May 11, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and address of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On May 22, 2001, from 8 a.m. to 10 a.m., the meeting will be closed to the public to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending and future device issues. In addition, the committee will discuss and review trade secret and/or confidential commercial information presented by a sponsor.

FDA regrets that it was unable to publish this notice 15 days prior to the May 21 and 22, 2001, Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs

concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 4, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Monica Oliver

Bonnie Malkin

Bonnie Malkin,
Special Assistant to the Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S